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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,799	01/11/2001	Thomas R. Porter	P00639US3	1046

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EXAMINER
SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 11/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application N .	Applicant(s)	
	09/758,799	PORTER, THOMAS R.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/6/02; 1/11/01* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53-78* is/are pending in the application.

4a) Of the above claim(s) *53-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *66-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II, claims 66-78 in Paper No. 4 is acknowledged.

Claims 53-65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4.

Claims 66-78 are under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 66-78 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "smaller vessels" in claim 66 and “stable microbubbles” in claim 75, appear to be relative terms which renders the claim indefinite. The term "smaller vessels" or “stable microbubbles” are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In effect, what is the point of reference or nature of comparison in determining the smaller vessels or stable microbubbles.

D uble Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 66-79 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 5,648,098; claims 1-24 of US Patent 6,197,345; claims 1-17 of US Patent 5,980,950. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims appear to overlap in scope.

The instant case is directed to methods of relieving trauma associated with obstruction of smaller vessels distal to a thrombus site comprising the same process steps as those of patented claims. The instant claims differ from the patented claims by their intended use. However, the intended use of the patented claims are directed for treating thrombosis and thus alleviating the surrounding tissue trauma. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to practice the instant claims when in possession of the patented claims.

Claim R jections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 66-72 are rejected under 35 U.S.C. 102(e) as being anticiopated by US Siegel Patent 5,695,460 (Siegel).

Siegel discloses methods of for utilizing a combination of ultrasonic energy and an echo contrast agent containing microbubbles for dissolving blood clots or other vascular obstractions (see abstract). Siegel specifically discloses the use of echo contrast agents containing dodecafluoropentane and sonicated albumin (see col 2, lines 48-57). Siegel further discloses the use of a thrombolytic agent in combination to the contrast agents mentioned above (see col 3, lines 14-40, col 9-14, claims 1, 10, 15). Finally, Siegel discloses the use of Albunex as the suitable sonicated albumin. Albunex contain microbubbles having average diameter size within 2-10 micron (see de Jong abstract, Ultrasonic 1993; 31(3):175-181). Therefore, Siegel anticipates the limitations of the instant claims.

Claim Rej ctions - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 66-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegel in view of Feinstein US Patent 4,572,203 (Feinstein) and Cerny et al US Patent 4,957,656 (Cerny) and Schutt US Patent 5,605,673 (Schutt).

The teachings of Siegel is described above. Siegel fails to specifically disclose the optimal concentrations for the albumin and the carrier.

Feinstein and Cerny collectively set forth various suitable concentrations and methodologies for employing albumin and a dextrose carrier system. Feinstein and Cerny teach methods of formulating Albunex echo contrast agent or similar type protein-shelled, gaseous microspheres in the field of ultrasound imaging. (see Feinstein, col 2, lines 46-68, col 8, lines 1-46, claims 1, 18-19; and Cerny, col 8, and claims 1, 2, 4-5). Feinstein and Cerny also acknowledge the use of their contrast agents in treating blood

flow abnormalities (see Feinstein, col 8, lines 1-10; Cerny incorporates the teachings of Feinstein in his patent). However, Feinstein and Cerny do not employ perfluorinated gases in their microbubble containing contrast agents in treating thrombus associated blood flow abnormalities.

Schutt provides for the use of various types of perfluorinated gases such as perfluorobutane and perfluoropropane in protein-shelled gaseous microbubbles in ultrasound contrast agents. (see abstract, col 16, lines 1-30). Schutt also suggests the use of his pefluorocarbon containing microbubbles in enhancing coronary flow with thrombolytic agents (col 11, lines 28-33).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to optimize the concentrations of albumin and dextrose in the Siegel's formulations, as suggested in Feinstein and Cerny, by routine experimentation, and further substitute the decafluorpentane of Siegel with other perfluorocarbons such as perfluorbutane or perfluoropropane, because as shown by Schutt, such moeities are considered to be art equivalent, and absence of showing unexpected results, they are expected to provide similar therapeutic results.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss
November 10, 2002

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200